

23476

IN THE U.S. PATENT AND TRADEMARK OFFICE

Inventor	Maria GAZDAG et al	
Patent App.	10/564,017	
Filed	15 May 2006	Conf. No. 3986
For	PROCESS FOR THE PREPARATION OF CHIRALLY PURE N-(TRANS-4-IS	
Art Unit	1621	Examiner Puttlitz, K

Hon. Commissioner of Patents
Box 1450
Alexandria, VA 22313-1450

RESPONSE

This is in response to the Office Action mailed
11 May 2009.

The sole claim that the Examiner will examine at this time is claim 5 directed to Crystals of nateglinide in the "G" form having a melting point of 100 to 109°C as well as the indicated IR and Raman spectral data. The Examiner has found four published US Patent Applications, namely, US Patent Applications 20050075400; 20050014949; 20040181089; and 20040116526, each of which discloses in Figures 6 and 40 the same compound, a crystalline form of nateglinide called the "G" form. The Examiner argues that each of these published US Patent Applications anticipates the Applicants' Crystals of nateglinide in the "G" form according to claim 5.

Applicants wish to make it clear that the crystalline form of nateglinide called the "G" form in all four published US patent applications cited by the Examiner, all assigned to Teva Pharmaceuticals, is not the same crystalline form of nateglinide covered in claim 5 of the present application. Just because the present Applicants and the applicants in the four cited patent applications both called their crystalline form of nateglinide, the "G" crystalline form, does not mean that the two forms are identical.

In paragraph [0095] of US 2005/0075400 A1 YAHALOMI et al unambiguously state that their crystalline form of nateglinide, which they designated Form G is an isopropyl solvate of nateglinide which has an isopropyl alcohol content of from about 12% to about 30%. Moreover in the Summary of the Invention in column 4 of US Patent 7,148,376 B2 to YAHALOMI et al, the designated nateglinide Form G is a solvate crystal. In other words Form G is a crystalline form having bound solvent. The isopropyl alcohol ("IPA") solvent is a part of the crystalline structure (solvate). This crystal structure basically differs from solvent-free crystals, from hydrates, and from the crystals having other solvents in bound form. Their characteristic physical data necessarily differ from each other.

In the present application the processes for the preparation of nateglinide Form G are described in Examples 1 and 3. In these processes for preparing nateglinide Form G, isopropyl alcohol is not employed at all, so Applicants' crystal Form G can not be an isopropyl alcoholic solvate. The only similarity between the present Form G nateglinide and the Form G of nateglinide disclosed in the cited YAHALOMI et al references is the name Form G. When Applicants gave the name Form G to their new nateglinide crystal they were not aware of the YAHALOMI et al patent applications. By coincidence YAHALOMI et al gave the same name to a completely different crystal form of nateglinide. Thus none of the cited YAHALOMI et al references provides a basis to reject claim 5 as anticipated under 35 USC 102.

Furthermore the fact that the YAHALOMI et al crystalline nateglinide Form G is an isopropyl solvate of nateglinide which has an isopropyl alcohol content of from about 12% to about 30% provides a basis for a significant difference in terms of structure from the crystals of nateglinide in present claim 5. In view of the significant difference in structure between the presently claimed crystalline Form G of nateglinide, which is clearly not a solvate of isopropyl alcohol and the crystalline Form G of nateglinide disclosed in the four cited references, which clearly is a solvate of isopropyl alcohol, none of the YAHALOMI et al reference provides a basis to reject claim 5 as obvious under 35 USC 103.

In view of the fact that Applicants' crystalline Form G of nateglinide is patentably distinguishable over the four cited YAHALOMI et al references, Applicants ask that the Examiner re-join process claims 1, 2 and 11, directed to the preparation of the Applicants' crystalline Form G of nateglinide, and examine these claims with claim 5. Under the PCT Practice the structure of the Applicants' crystalline Form G of nateglinide is a common technical feature linking all of these claims, that the prior art neither discloses nor suggests. Similarly Applicants also ask that the Examiner re-join process claim 7 as well because claim 7 is directed to a process for preparing crystalline Form H of nateglinide where the Applicants' crystalline Form G of nateglinide is the starting material. Once again under the PCT Practice the structure of the Applicants' crystalline Form G of nateglinide is a common technical feature linking all of these claims, that the prior art neither discloses nor suggests.

Applicants believe that claims 1, 2, 5, 7 and 11 are patentably distinguishable over the cited prior art and that no rejection should be maintained against these claims in view of the cited prior art under either 35 USC 102 or 103. Thus Applicants believe that all of the claims are allowable and earnestly solicit a response to that effect.

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